

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

UNITED STATES OF AMERICA,)	
<i>ex rel.</i> JAMES ALLEN,)	
)	
Plaintiffs,)	Civil No. 11-22 (DWF/AJB)
)	
)	
v.)	
)	
)	
GUIDANT CORPORATION, <i>et al.</i>)	
)	
Defendants.)	

JOINT RULE 26(f) REPORT AND DISCOVERY PLAN

As required by Fed. R. Civ. P. 26(f) and the Court's April 15, 2011 Order, the parties met in person and conferred regarding discovery and case management issues. As a result of that meeting and further consultation between counsel, the parties submit the following Joint Rule 26(f) Report and Proposed Discovery Plan.

1. **DATE AND PLACE OF THE MEETING AND IDENTIFICATION OF THE PARTIES AND THEIR ATTORNEYS**

- a. The parties held a Rule 26(f) conference on May 26, 2011 at the offices of Shook Hardy & Bacon, L.L.P., 1155 F St. NW, Washington, D.C.
- b. The Plaintiff is the United States of America. The United States was represented at the meeting by:

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Chad A. Blumenfield, Esq.
(*via phone*)
U.S. Attorney's Office
600 U.S. Courthouse
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The Relator is James Allen. Mr. Allen resides at 488 Central Ave., Lancaster, NY 14208. He was represented at the meeting by:

Dennis R. McCoy, Esq.
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1100 M&T Center
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Buffalo, NY 14203
(716) 566-1560

James I. Myers, Esq.
Myers, Quinn & Schwartz, LLP
5500 Main St., Ste. 312
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The Defendants are Guidant LLC, Guidant Sales LLC, Cardiac Pacemakers, Inc. and Boston Scientific Corporation. The Defendants were represented at the meeting by:

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Jeff Kruse, Esq.
Boston Scientific Corp.
4100 Hamline Avenue North
St. Paul, MN 55112
(651) 581-3403

- c. Name of insurance carriers that may be liable for payment of any damage award.

Defendants have not to date identified any policies of insurance providing coverage applicable to this case for either defense or indemnity.

1. DESCRIPTION OF THE CASE

a. Jurisdictional basis of case

The Court has subject matter jurisdiction under 28 U.S.C. § 1331 (Federal question jurisdiction), as this action arises under the False Claims Act, 31 U.S.C. § 3729 *et seq.* and federal common law. The plaintiff in this case is the United States, and therefore subject matter jurisdiction is also appropriate under 28 U.S.C. § 1345 (United States as plaintiff).

b. A brief narrative of the facts giving rise to the lawsuit, including a description of legal claims and defenses

i. *Brief Narrative of Government's complaint*

The United States brings this action under the False Claims Act, 31 U.S.C. § 3729(a)(1) (2006) and the common law action of unjust enrichment to recover losses from false claims that defendants Boston Scientific Corporation, Guidant LLC, Guidant Sales LLC, and Cardiac Pacemakers, Inc. caused to be submitted by health care providers to the Medicare program.

The United States contends that Guidant LLC (formerly Guidant Corp.), Cardiac Pacemakers, Inc. (CPI), and Guidant Sales LLC (formerly Guidant Sales Corp.) (collectively "Guidant") knew as early as April 2002 that an implantable cardiac device it manufactured and sold, known as the Prizm 2, contained a potentially life-threatening defect. The Government's complaint alleges that Guidant took corrective manufacturing actions to fix the problem on April 16, 2002 and November 13, 2002. The complaint states that even after taking these actions, Guidant continued to sell the defective versions of the devices. Similarly, the Government contends that Guidant knew as early as November 2003 that an implantable cardiac device it manufactured and sold, known as the Renewal, contained a similar, potentially life-threatening defect. Even after Guidant took corrective manufacturing action to remedy the defect, Guidant continued to sell the defective versions of the devices.

Boston Scientific Corp. acquired Guidant in 2006.

ii. *Brief Narrative of Relator's complaint*

The Relator supports the allegations in the Government's complaint. The Relator's complaint additionally alleges that Guidant became aware in 2002 and 2003 of certain defects in its devices which affected the safety and efficacy of the devices. Relator alleges that Guidant withheld this information from doctors, Medicare, the

Veteran's Administration and others, and instead marketed and sold the devices as free of defect when it had reason to believe they were not.

iii. *Brief Narrative of Defenses:*

Defendants deny the United States' and Relator's (collectively "Plaintiffs") allegations. Defendants deny that the devices at issue were defective. Defendants further deny that they, individually or collectively, caused any false claims to be submitted. Defendants further deny that the Guidant devices about which Plaintiffs complain were not "reasonable and necessary" for the Medicare patients for whom they were prescribed. Further, Defendants deny that the characteristics of the Guidant devices about which Plaintiffs complain were material to any payment decision made by the United States. Defendants further state that the United States has previously settled and released a substantial portion of the claims Plaintiffs here re-allege, and that the United States suffered no damages as a result of the conduct alleged in any event. Defendant Boston Scientific also states that it is not a proper party to this action, which is premised entirely on allegations of conduct that took place between 2002 to 2005, before Boston Scientific acquired Guidant in 2006.

c. A summary itemization of the dollar amount of each element of the alleged damages

The Parties propose that the United States and the Relator provide the Defendants with the itemized damages summary by June 27, 2011.

3. PLEADINGS

a. A statement of whether the Complaint and all responsive pleadings have been filed, and whether any party proposes to amend its pleadings

All responsive pleadings have been filed, and no party contemplates amending its pleadings at this time.

Defendants previously filed a motion to dismiss Relator's case on September 24, 2010 while this matter was pending in the U.S. District Court for the Western District of New York. Based on the government's filing of its Complaint in Intervention and its taking control of this *qui tam* case pursuant to statute, Defendants propose to re-file the motion to dismiss by October 15, 2011 — two weeks after the date for filing amended pleadings — to take into account the changed nature of the litigation following the intervention of the United States.

- b. The date by which all motions which seek to amend the pleadings or add parties will be filed

The parties propose October 1, 2011.

- c. Whether a jury trial is available under the law, and whether a jury trial has been timely demanded

A jury trial is available under the law and has been timely demanded by all parties to this action.

4. DISCOVERY PLAN

- a. Date by which the initial Rule 26(a)(1) disclosures of witnesses, documents, itemized damage computations and insurance will be completed

The parties propose that Rule 26(a)(1) disclosures of witnesses and itemized computation of damages will be exchanged by June 27, 2011.

- b. Whether the parties wish to engage in any method of alternative dispute resolution following Rule 26(a)(1) disclosures but before formal discovery is commenced

i. *Plaintiffs' Position*

The United States is willing to engage in mediation following the exchange of Rule 26(a)(1) disclosures as the Court believes is appropriate, but does not wish to postpone the commencement of formal discovery beyond July 5, 2011, according to the United States' proposed schedule.

If the Court does postpone discovery for mediation, however, the United States proposes that discovery commence on October 1, 2011, even if mediation is ongoing at that time. Moreover, to avoid the inevitable delay that often comes with the production of electronically stored information, the United States further proposes that the parties exchange initial requests for production of documents no later than August 1, 2011, and meet and confer as soon as practical thereafter regarding the manner and scope of production and any search terms to be used, as contemplated by Federal Rule of Civil Procedure 26(f)(3)(C).

ii. *Defendants' Position*

Defendants wish to engage in mediation with the Court following the exchange of Rule 26(a)(1) disclosures on June 27, 2011 and before formal discovery is commenced on October 1, 2011 according to Defendants' proposed schedule. Defendants do not object to the parties exchanging initial requests for production of documents on or after August 1, 2011, and meeting and conferring as soon as practical thereafter regarding the manner and scope of production and any search terms to be used.

c. Whether discovery should be conducted in phases, or limited to or focused upon, particular issues

i. *Plaintiffs' Position*

The Plaintiffs propose the following phases for discovery:

Commencement of Discovery:	July 5, 2011
Last day to serve written discovery:	May 4, 2012
Close of Fact Discovery:	June 5, 2012
Close of Expert Discovery:	October 1, 2012

The Plaintiffs also propose that the parties should not limit discovery to particular issues at this time, but reserve all rights afforded to them to object to any discovery requests.

ii. *Defendants' Position*

The Defendants propose the following:

Commencement of Discovery:	October 1, 2011
Last day to serve written discovery:	March 14, 2012
Close of Fact Discovery:	April 15, 2012
Close of Expert Discovery:	October 1, 2012

The Defendants also propose that discovery should not be conducted in phases, other than as described above. Defendants propose that document and fact deposition discovery previously completed in related litigation, however, not be repeated absent an agreement between the parties or a court order.

Because the relevant dates are scattered throughout this joint report, for the Court's convenience, attached as an exhibit are the parties' proposed dates in chronological order. The dates as to which there is agreement are **bolded**. As the Court will observe, the differences between the parties relate to: 1) whether or not to begin formal discovery during early mediation; and 2) the structure of expert discovery.

d. The date by which each party shall disclose the identity of expert witnesses and their reports under Rule 26(a)(2)(A) and (B)

i. *Plaintiffs' Position*

The Plaintiffs propose as follows:

Disclosure of identity of experts:	June 12, 2012
Expert reports due:	July 17, 2012
Disclosure of rebuttal experts and rebuttal reports (if any):	August 7, 2012
Close of expert discovery:	October 1, 2012

ii. *Defendants' Position*

The Defendants propose as follows:

Plaintiffs' expert reports due (plaintiffs shall tender reasonable dates for depositions of any experts for whom reports are proffered simultaneously with the service of the reports)	May 15, 2012
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Completion of plaintiffs' experts' depositions	June 15, 2012
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Defendants' expert reports due (defendants shall tender reasonable dates for depositions of any experts for whom reports are proffered simultaneously with the service of the reports)	July 15, 2012
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Completion of defendants' experts' depositions August 15, 2012

Plaintiffs' rebuttal expert reports due (if any) (plaintiffs shall tender reasonable dates for depositions of any experts for whom rebuttal reports are proffered simultaneously with the service of the reports) September 1, 2012

Completion of plaintiffs' rebuttal experts' depositions (if any) October 1, 2012

e. The number of interrogatories each party shall be permitted to serve

The parties propose that the Defendants (collectively) have 45 interrogatories, that the United States have 33 interrogatories, and that the Relator have 12 interrogatories. The United States and Relator may distribute between them the number of interrogatories each party may ask of Defendants without leave of Court.

f. The number of depositions (excluding depositions of expert witnesses) each party shall be permitted to take

The parties propose that the Defendants (collectively) can take 28 depositions, that the United States can take 20 depositions, and that the Relator can take 8 depositions, except that the United States and Relator may distribute the number of depositions each has between them without leave of Court.

g. The number of expert depositions each party shall be permitted to take

i. *Plaintiffs' Position*

The Plaintiffs propose one deposition per expert, regardless of whether that expert also authors a rebuttal report.

ii. *Defendants' Position*

The Defendants agree, unless a Plaintiffs' expert submits both an initial and a rebuttal report; in such a situation, Defendants may conduct a supplemental deposition following the production of the rebuttal report limited to the rebuttal report's topics.

h. Additional Discovery Provisions

i. *Defendants' Position*

Defendants believe that separate-party Plaintiffs must coordinate as to avoid duplicative and/or harassing discovery. Defendants similarly believe that separate-party Defendants must coordinate so as to avoid duplicative and/or harassing discovery. Defendants also believe that the parties must use their best efforts to avoid duplicating discovery of documents, data and information that has been exchanged in related litigation or proceedings.

ii. *Plaintiffs' Position*

The Plaintiffs submit that the Federal Rules of Civil Procedure, specifically as set forth at Fed. R. Civ. P. 26(c) (protective orders), provide an adequate procedure for addressing any disagreements that may arise as to the scope or conduct of discovery, and that there is thus no need at the outset of discovery, before any requests have even been served, for any limitations on the discovery rights of any party in this action.

5. CLOSE OF DISCOVERY AND NON-DISPOSITIVE MOTIONS

The parties propose that all discovery be completed by October 1, 2012, and that non-dispositive discovery motions (not including *Daubert* motions or motions *in limine*) be due by October 15, 2012.

6. DISPOSITIVE MOTIONS AND TRIAL

- a. Date by which all dispositive motions shall be served, filed and heard by the Court: The parties propose that dispositive motions be filed by November 19, 2012, and heard by the Court on or about January 25, 2013.

- b. Date by which the case will be ready to commence trial: The parties propose that the case will be ready for trial on or after March 25, 2013.
- c. The number of expert witnesses each party expects to call at trial: The parties do not anticipate either side will call more than four experts at trial.
- d. Estimated trial time including jury selection and instructions: The parties anticipate that the trial will last 15 to 20 trial days.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

JOHN R. MARTI
ATTORNEY FOR THE UNITED STATES
*Acting under authority conferred
by 28 U.S.C. § 515*

Dated: June 10, 2011

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